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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/504,389 02/15/00 PERLIN

M PERLIN-8

EXAMINER

HM12/0821

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MARKER A

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

08/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/504,389

Applicant(s)

PERLIN, MARK W.

Examiner

Amy Hartter

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Attachment to PTO form 948* . ✓

Answer to Traversal

The Applicant indicates in the traversal that Claim 1 which is part of Group I which has the limitation of "detecting the fragments to form a size standard signal ... transforming the sample signal into size coordinated using the size standard signal ...". This the Applicant claims can be considered proof of a linear equation. The Applicant continues with this line of reasoning stating that Group III has the limitation of "comparing the first signal with the second signal ... to form a comparison". This the Applicant further states can be considered a linear equation. The Applicant continues by stating that because all of the groups have the influence of the linear equation that they should not be in separate classes or subclasses, and thus separate Groups.

The examiner cannot concur with these arguments. The examiner does not grasp how the transformation of a signal evolves into a linear equation. Nor does the examiner comprehend how the comparison of two signals falls into the category of a linear equation. Many different types of signals can be compared the examiner offers the example of streetlights manifesting themselves in green and red as a comparison of signals that does not become a linear equation. Therefore this restriction is made final.

Detailed Action

Claims 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant makes the assertion in Claim 17 and

subsequent dependent claims that the applicant has invented " a method for resolving DNA mixtures". However the Applicant fails to inform the reader what type of resolution is employed. The Applicant could be attempting a type of resolution that would employ electrophoresis that should involve separating and resolving by those means. However the Applicant could also mean DNA resolution by such methods as HPLC or the resolution of an image of DNA on the screen in some type of modeling endeavor. Thus Claims 17-22 are vague and indefinite as to what type of resolution is meant by the claims.

Claims 19 and 21 are also rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. This is due to the fact that it is not clear to the reader how a complicated entity such as a matrix or vector as is claimed in 19 and 21 could be reduced to a linear equation. Thus claims 19 and 21 are rejected on the basis of being vague and indefinite.

Claims 17-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the DNA mixture, does not reasonably provide enablement for the linear equation and the solution to the linear equation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to deduce the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 456

(BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ 2D 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of those in the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

Although the Applicant provides the reader with the idea of using a linear equation to resolve a DNA mixture it does not tell us what exactly that equation is or its solution so that one might infer the equation from the solution without its manifestation in the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. § 102 (b) as being clearly anticipated Menchen et al. patent number 5,759,369 or Grossman patent number 5,374,527.

The Menchen et al. and Grossman patents basically describe an electrophoretic method to resolve portions of DNA as is claimed in the instant invention. The Menchen et al patent states the following:

Also disclosed is an electrophoresis method employing the separation methods, which permits high-resolution separation of polynucleotides, especially in DNA sequencing operations. (Please see abstract page 1)

The Grossman patent states the following:

By electrophoretically separating a mixture of single-stranded DNA sequencing fragments in a capillary tube. (Please see abstract page 1).

The instant application proceeds with the declaration of "a method for resolving DNA mixtures". It can certainly be deemed that two types of resolution could be considered to be electrophoresis and separation within a capillary tube. Thus this art can certainly be considered as legitimate knowledge in the art. Although the Applicant does not state clearly that either of the resolution techniques that they employed were that of electrophoresis or capillary separation, they are certainly techniques that reside within the broadness of the claim.

The Applicant will also please note that the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title includes a system, which is not in the elected claims and also fails to indicate that the elected invention is directed to resolving DNA mixtures.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment

for PTO-948 (rev. 03/01 or earlier)". Due to the above notification applicants are required to submit drawing corrections within the time period set for responding to this Office Action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Conclusion

Any inquiry concerning this communication or earlier communications from this examiner should be directed to Amy Hartter whose telephone number is (703) 305-1696. The examiner can normally be reached Monday-Friday from 8:00 to 4:30 p.m. (Eastern Time).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached at (703) 305-4028. The fax phone numbers for the group are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Patent Analyst, Kim Davis, whose telephone number is (703) 305-3015 or to the Technical Center receptionist whose telephone number is (703) 308-0196.



Amy Hartter

(703) 305-1696



ARDIN H. MARSCHEL
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.
